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From: Brian Schar [mailto:schar@cardica.com] Sent: Monday, March 20, 2006 12:54 PM

To: AB93Comments

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Subject: Comments to proposed rules published at 71 Fed. Reg. 48

Comments to proposed rules re: Changes to Practice for Continuing Applications:

I am a patent attorney in Redwood City, California. I am in-house counsel at a medical device company which, although publicly-traded, is considered a small entity. I am writing in regard to the proposed rules entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (2006) (to be codified at 37 C.F.R. Part 1) (hereinafter "Proposed Rules"). I am concerned about several points of the Proposed Rules, some of which could be particularly harmful to small entities:

- 1. According to statute, when a patent application is filed, "[t]he Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." (35 U.S.C. §131) (emphasis added).. The United States Code does not provide the Director with discretion over whether to accept an application for filing. Rather, the United States Code mandates that the Director shall cause examination to be made. Any rule to the contrary, including the proposed rules, is inconsistent with the statute. It is axiomatic that statutes take precedence over regulations. Thus, any proposed rule that grants discretion in the Director as to whether a particular application will be examined violates 35 U.S.C. §131.
- 2. Proposed rule 37 C.F.R. §1.114 violates the applicant's duty of disclosure under 37 C.F.R. §1.56, by requiring the applicant to obtain the permission of the Director before discharging its duty. If the Director does not grant permission for the applicant to perform its duty, the patent may be so weakened upon issue that the statutory presumption of validity under 35 U.S.C. §281 is gutted.

At times, references do not become available to an applicant until late in prosecution, even after payment of the issue fee. Such references may come from a foreign search report for a counterpart application, from a patent search on a different invention, or from sheer serendipity. Regardless of the source of those references, applicants have a duty to disclose them to the Examiner. In a later phase of prosecution, a Request for Continued Examination (RCE) is typically filed to allow the Examiner to consider that reference. Indeed,

according to MPEP 609.04(b)(IV), after payment of the issue fee, the applicant must petition to withdraw the application from issue and file an RCE in order for the Examiner to consider a newly-discovered reference. If the Director does not grant permission to cite the newly-discovered reference, the patent application will be weakened significantly upon issue, as infringers will attack the validity of the issued patent on the grounds that the newly-discovered reference was not considered by the Patent Office.

Further, the citation of additional art can only improve patent quality. Improving patent quality is a goal of the proposed rules: "[t]he revised rules should also improve the quality of issued patents." (page 48). Thus, the rationale for the proposed rules runs counter to the requirement to obtain permission to file an RCE for the purpose of submitting newly-discovered art.

At a minimum, the proposed rules should be amended to allow the filing of an RCE as of right for the purpose of considering additional art, without the requirement to petition the Director.

- 3. Proposed rule 37 C.F.R. 1.78(f) punishes small entities, particularly unsophisticated ones. Consider hypothetical Smallco, which is too small to have in-house counsel. Smallco may engage two different outside counsel, Adams and Jefferson, or may have engaged outside counsel Adams up to a certain date, after which Smallco engaged a different outside counsel Jefferson. Both of these situations are not uncommon. The person at Smallco who is responsible for patent prosecution is not an attorney, which is why that person relies on outside counsel, and is completely unaware of proposed rule 37 C.F.R. 1.78(f). As a result, that person does not know that he or she should disclose to Jefferson the patent applications being prosecuted by Adams, and vice versa. That lack of disclosure will be attacked as inequitable conduct in infringement litigation, through no fault of Smallco. In contrast, a large company typically has many different inventors, and in-house counsel who are familiar with the rules and can track large numbers of files across different law firms.
- 4. Additionally with regard to proposed rule 37 C.F.R. 1.78(f), the phrase "substantial overlapping disclosure" has no commonly-understood meaning in patent law and is undefined in the rules. If the phrase is intended to mean that the words of the different applications are substantially the same, then proposed rule 37 C.F.R. 1.78(f) will be burdensome, but manageable by sophisticated entities. If the phrase is intended to mean that both applications are simply directed to inventions in the same area of technology, then proposed rule 37 C.F.R. 1.78(f) will be burdensome and almost unmanageable both by applicants and the Patent Office. Consider an automobile manufacturer. If that manufacturer files two separate applications to two different automotive inventions on the same day, with different specifications for each application,

would those applications be considered "substantial overlapping disclosure" because they are both in the automotive field? The vagueness of this proposed rule is fatal.

5. Restrictions on continuations-in-part (CIPs) would be catastrophic in combination with a first-to-file system. Typically, during product design, a patent application will be filed early in the design process during the brainstorming stage, to broadly cover different aspects of that product. As design continues, some aspects change and others become more detailed. As a result, a CIP is often filed in the middle of the design process when prototypes are built. Then, as the product moves on to production, various changes are often made to take advantage of lessons learned from the prototype. As a result, a second CIP is often filed to cover various aspects of the final production version of the product.

In a first-to-file system, the inventors must "race to the patent office." That is, inventors are forced to submit patent applications earlier in the design process than they otherwise would, where those applications are directed to very early stage brainstorming. As a result, filing of a CIP to reflect an actual prototype or product, as opposed to that early brainstorming, becomes critical. First-to-file practice would penalize small inventors once; restriction of CIP practice would penalize them yet again.

6. The Petitions Branch is already overwhelmed, and can take well over a year to deliver a response to a petition. Indeed, this writer is currently waiting in March 2006 for a decision on a petition filed in December 2004. As a result of the proposed rules, the Petitions Branch will have to consider a large number of new petitions just requesting permission to file RCEs based on newly discovered art, such as from foreign prosecution. According to the proposed rules, in fiscal year 2005, the Patent Office received over 52,000 RCEs. Even cutting that number in half, the Petitions Branch will have to process 25,000 petitions each year requesting permission to file an RCE. In addition, the Petitions Branch will have to handle petitions from applicants that wish to file continuations and CIPs. According to the proposed rules, in fiscal year 2005, the Patent Office received over 44,000 continuation and CIP applications. Cutting that number in half still leads to 22,000 petitions each year. Consequently, the Petitions Branch can reasonably expect to receive at least 47,000 new petitions each year, on top of the existing backlog. The resultant backlog of applications will become staggering as applicants wait years for a decision from the petitions branch before prosecution can proceed.

Thank you for considering these comments.

Sincerely,

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